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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/845,956  | 04/30/2001  | Nikiforos Kollias    | J&J-2022            | 4497             |
| 27777   | 7590        | 11/16/2005           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | AHMED, AAMER S      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3763                |                  |

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/845,956

Applicant(s)

KOLLIAS ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☒ Claim(s) 20 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/28/05, 07/25/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 20 and 21 are objected to because of the following informalities: the term "shear" is misspelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-9, 11-13, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hai EP 0429842 A2. Hai ('842) discloses a method for transporting a molecule through a mammalian barrier membrane of at least one layer of cells comprising the steps of ablating the membrane with a shear device comprising a sheet containing at least one opening and a shear member, where the sheet is contacted with the membrane such that a portion of the membrane is forced through the opening and ablates the portion of the membrane exposed through the opening; and utilizing a driving force to move the molecule through the perforated membrane. Furthermore, Hai ('842) discloses a wherein the shear member is a shear blade and wherein, the membrane is forced into the opening by a pressure, the membrane, wherein the pressure force is mechanical pressure. Moreover, Hai ('842) discloses that the shear device further comprises a driving unit to move the blade and wherein the driving unit is powered manually by the user of the device; and wherein the driving unit is powered by an electric motor; and wherein the membrane is skin. In addition, Hai ('842) discloses, that the driving force is a

concentration gradient; and wherein the pharmaceutical agent is a peptides or proteins, and wherein the shear blade member moves parallel to the shear sheet (see abstract and Examples 5, 7 and 8 to 11).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hai ('842) in view of Svedman U.S. Patent Number 5,441,490. Hai ('842) discloses the method as described above in reference to claims 1 and 3. Hai ('842) fails to disclose that the pressure force is suction nor that the membrane in human skin. Svedman ('490) discloses a similar method of delivery in which is described the use of suction on the human skin to deliver a fluid (see abstract). It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the method as described by Hai ('842) by incorporating

suction of human skin as taught by Svedman ('490) in order to increase micro-circulation (col. 2 line 10).

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hai ('842) in view of McMichael WO 89/01338. Hai ('842) discloses the method as described above in reference to claim 12. Hai ('842) fails to disclose that the molecule is a vaccine against *Staphylococcus aureus*. McMichael discloses a similar method in which a vaccine for *Staphylococcus aureus* is administered (see abstract). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Hai ('842) by incorporating the delivery of the vaccine for *Staphylococcus aureus* in order to alleviate symptoms of acquired immune deficiency syndrome in a disease victim (McMichael '822 page 15 line 15).

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hai ('842) in view of Cormier et al U.S. Patent Number 6,219,574. Hai ('842) discloses the method as described above in reference to claim 16. Hai ('842) fails to disclose that a glucose molecule is transported from within and out through the membrane. Cormier et al ('574) discloses a similar method in which a glucose molecule is transported out through the membrane, (col. 1 line 12). It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the method of Hai ('842) by incorporating the transportation of glucose from the membrane as taught by Cormier et al ('574) in order to sample body fluids for analytical testing (col. 1 line 12).

Claim 18, 19 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over Sun et al U.S. Patent Number 6,678,554.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2). Hai ('842) discloses the method as described above in reference to claim 6. Hai ('842) fails to disclose an impedance sensor. Sun et al ('554) describes a similar method in which an impedance sensor is used to measure the impedance of the barrier membrane (col. 2 line 8). It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the method of Hai ('842) by adding an impedance sensor as taught by Sun et al ('554) in order to measure compositional changes (col. 2 line 8).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hai ('842) and Sun et al ('554) and further in view of Lattin et al U.S. Patent Number 4,406,658. Hai ('842) and Sun et al ('554) describe the method as described above in reference to claim 22. Neither Hai

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('842) nor Sun et al ('554) disclose a microprocessor. Lattin et al ('658) discloses a similar method in which a microprocessor receives measurements from an impedance sensor (col. 12 line 45). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Hai ('842) and Sun ('554) by adding a microprocessor as taught by Lattin et al ('658) in order to control the delivery of molecules (col. 12 line 45).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

|                   |                                |
|-------------------|--------------------------------|
| US 4963360 A      | Argaud; Albert                 |
| US 5636632 A      | Bommannan; Durairaj et al.     |
| US 5042975 A      | Chien; Yie W. et al.           |
| US 20020010414 A1 | Coston, Anthon y F. et al.     |
| US 5336213 A      | D'Angelo; Joseph P. et al.     |
| US 6629949 B1     | Douglas; Joel S.               |
| US 6607513 B1     | Down; James et al.             |
| US 6132755 A      | Eicher; Joachim et al.         |
| US 20040059282 A1 | Flock, Stephen T. et al.       |
| US 6780171 B2     | Gabel; Jonathan B. et al.      |
| US 6652478 B1     | Gartstein; Vladimir et al.     |
| US 3964482 A      | Gerstel; Martin S. et al.      |
| US 5879326 A      | Godshall; Ned Allen et al.     |
| US 5003987 A      | Grinwald; Paul M.              |
| US 5983136 A      | Kamen; Dean L.                 |
| US 6440096 B1     | Lastovich; Alexander G. et al. |
| US 5250023 A      | Lee; Hai Bang et al.           |
| US 5084006 A      | Lew; Patrick J. et al.         |
| US 5127163 A      | Locke; David R.                |
| US 6537242 B1     | Palmer; Phyllis J.             |
| US 5667491 A      | Pliquett; Uwe et al.           |
| US 5494679 A      | Sage, Jr.; Burton H. et al.    |
| US 6532386 B2     | Sun; Ying et al.               |
| US 20040236248 A1 | Svedman, Pat                   |
| US 6048337 A      | Svedman; Pal                   |
| US 5224927 A      | Tapper; Robert                 |

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|               |                                 |
|---------------|---------------------------------|
| US 6918901 B1 | Theeuwes; Felix et al.          |
| US 6083196 A  | Trautman; Joseph Creagan et al. |
| US 6322808 B1 | Trautman; Joseph Creagan et al. |
| US 6050988 A  | Zuck; Michael G.                |


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A.A.



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